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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09 004,395	01 08 1998	ROBERT D. GILMORE JR.	97.429	1172

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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/01/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/004,395

Examiner

N. M. Minnifield

Applicant(s)

GILMORE ET AL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 21-26, 28, 29 and 31-50 is/are pending in the application.
- 4a) Of the above claim(s) 31-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 21-26, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 2 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 4 ☒ Interview Summary (PTO-413, Paper No. 37)
- 5 ☐ Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

1. Applicants' amendment filed April 16, 2003 is acknowledged and has been entered. New claims 31-50 have been added.

2. Newly submitted claims 31-50 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are directed to a method for diagnosis of Lyme Disease. Also, please see original restriction requirement set forth in the paper mailed December 7, 1998.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 15-17, 21-26, 28 and 29 are being examined in the present application.

4. Claims 15-17, 21-26, 28 and 29 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Ge et al. 1997 (J. Bacteriology).

The claims (products and product by process) are directed to a recombinant *Escherichia coli* strain that expresses a protein that is identical or substantially identical to the protein of Ge et al. 1997 (J. Bacteriology).

Ge et al (J. Bacteriology, 1997) disclose a flagellin protein, FlaA, from *B. burgdorferi* having a molecular weight of 38 kD (abstract; p. 552). A lysate of *B. burgdorferi* showed strong reactivity to a protein of 38.0 kDa, which is consistent with the expression of *flaA* in growing cells (abstract). Ge et al disclose the protein sequence of the FlaA protein as well as the DNA sequence (Figure 1) and that the *B. burgdorferi* FlaA homolog contains a typical signal sequence at its N terminus including a positively charged N-terminal domain, a central hydrophobic segment and a signal peptidase I cleavage site; after cleavage the mature protein has a molecular weight of 36 kD (p. 553). Western blot analysis of cell lysates of *B. burgdorferi* indicates that a single band of approximately 38.0 kD reacted with antiserum (figure 5; p. 555). The prior art anticipates the claimed invention.

The prior art discloses the amino acid sequence as claimed, SEQ ID NO: 2; the conditions for preparing the FlaA protein are not relevant to the pending claims as they are directed to products.

5. Applicant's arguments filed June 25, 2001 have been fully considered but they are not persuasive. It is noted that this response to Applicants' arguments only addresses the arguments as they pertain to Ge I (J. Bacteriology, 1997). Applicants have argued that Ge I does not disclose, expressly or imply, the utility of FlaA protein as a diagnostic reagent. It is noted that the claims are directed to a product comprising a FlaA protein which the prior art discloses. The claims are not directed to methods of making or methods of diagnosis. In response to

the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Further, the products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

In response to applicant's arguments, the recitation of diagnostic reagent has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Further, preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure. *In re Gardiner*, 171 F.2d 313, 315-16, 80 USPQ 99, 101 (CCPA 1948).

Applicants have asserted that Ge I must be enabling and describe the claimed invention sufficiently to have placed it in the possession of a person of ordinary skill in the field of the invention; Ge I does not teach one of skill in the art how to accomplish a diagnostic assay with FlaA as a reagent or how to analyze results and data of such assay. It is noted that the claims are not directed to how to accomplish a diagnostic assay with FlaA as a reagent or how to analyze results and data of such assay. The claims are directed to a FlaA protein, which the prior art discloses. It is noted that a claim is anticipated if each element of the claim is found (in this case the FlaA protein), either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice.

6. Applicant's arguments filed April 16, 2003 have been fully considered but they are not persuasive. It is noted that Applicants' arguments have been previously addressed.

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the

statutory period, then the shortened statutory period will expire on the date the

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advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



N. M. Minnifield

Primary Examiner

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6-30-03